REMARKS

Claims 21-34 are in this case for consideration. Claims 31-34 have been added to more completely claim Applicant's elected invention. Support for claims 31-34 can be found, among other places, at pages 18-19 of Applicant's specification.

A. Prior Art Rejections

1. The Invention

Applicant has invented a novel method of posterior surgery for replacing fibrocartilage in damaged vertebral discs. In the posterior approach to spinal disc surgery, one makes the surgical incision(s) in the back of the patient. By contrast, in the anterior approach to spinal disc surgery, one makes the surgical incision in the front of the patient, typically in the abdominal region. Unlike existing anterior spinal disc surgeries, permanently articulating vertebral implant devices are inserted using Applicant's method through one or more minimally invasive posterior incisions near the site of the damaged vertebral disc. After an incision is made in Applicant's process, a partial discectomy is posteriorly performed to remove damaged fibrocartilage disc tissue. After the partial discectomy, at least two permanently articulating vertebral implant devices are posteriorly inserted to replace the disc tissue and permanently allow continued movement of the vertebrae with respect to one another in a way which generally approximates a healthy disc. In one embodiment, the permanently articulating vertebral implant devices are posteriorly inserted in pieces with supports being inserted first for ready attachment to facing vertebrae surfaces followed by insertion of a cushioning member, such as a spring, between the supports in order to connect the supports and form the completed articulating

vertebral implant device. To avoid damage to spinal nerve tissue and provide necessary balance, at least one vertebral implant device is preferably inserted on each side of a vertical medial plane defined by the spinous processes of the superior and inferior vertebrae.

2. The Cited Art Distinguished

Applicant's claims 21-23 and 25-30 have been rejected under 35 U.S.C. § 103(a) as being obvious over Michelson's U.S. Patent No. 6,436,098 ("Michelson patent") in view of Ralph's U.S. Patent No. 5,989,291 ("Ralph patent"). The Michelson patent discloses devices and accompanying processes which are used to *fuse* two vertebrae together. As stated in the first column of Michelson's patent, the "purpose of the present invention" is to "permanently eliminate all motion at that location." (Michelson patent, col. 1, lns. 37-46). This purpose is accomplished by using a "rigid" implant device that creates "a vertebra to vertebra bony fusion so as to assure the permanency of the result." *Id.*

The Michelson patent teaches away from Applicant's invention. *See McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed.Cir. 2001)(prior art references which "teach away cannot serve to create a prima facie case of obviousness"). Unlike the Michelson fusion devices and processes, it is not Applicant's objective to fuse two vertebrae together through and around an implant device so that relative movement between them is prevented. The objective of Applicant's process is exactly the opposite. By using permanently articulating vertebral implant devices, Applicant's process results in the placement of devices between the respective vertebrae which permanently allows continued movement of the vertebrae with respect to one another in a way which generally approximates a healthy disc.

While a posterior approach was previously known for *fusion* surgery, as acknowledged by Applicant is his August 23, 2006 Amendment and illustrated by the Michelson patent, this posterior approach was thought to be unavailable for arthroplasty (i.e., the insertion of permanently articulating implant devices). As explained in the declaration which accompanied Applicant's August 23, 2006 Amendment from William A. Brennan M.D., F.A.C.S., a neurosurgeon certified by the American Board of Neurological Surgery who has performed over two thousand spinal surgeries, it was commonly thought in the arthroplasty art that implanting two or more permanently articulating devices side-by-side, as disclosed in the present application, would not work because the two side-by-side devices would inhibit axial rotation. (Brennan Decl., ¶ 8). Such inhibition was considered to be a bad thing in the arthroplasty art because it was perceived as contrary to the objective of implanting a device which approximates the natural movement of the replaced disc.

By contrast, the objective of Michelson's fusion implants is to prevent continued movement of the fused vertebrae. For this reason, fusion surgeons do not worry about inhibiting axial rotation and, in fact, they affirmatively try to prevent any type of movement of the vertebrae with respect to one another. As such, to the extent the Michelson patent teaches use of implant devices which inhibit axial rotation, this is considered to be a good thing in the fusion art.

Not dissuaded by the conventional wisdom in his arthroplasty art, Applicant observed that in the lumbar region, for example, the facet joints naturally found in the human body act as a type of doorstop to prevent full rotational movement. Applicant also observed that

in cases where disc replacement devices have been anteriorly implanted in the lumbar region to allow full axial rotation, patient complications have arisen from excessive axial rotation.

Applicant reasoned that if full rotational movement was not necessary, articulating implant devices could be made smaller and inserted in a way which would inhibit rotational movement. Because of all the bone and nerve obstacles to such a posterior insertion, Applicant further reasoned that it would be best to insert two smaller articulating implant devices around the left and right sides, respectively, of the spinal cord/spinal nerve roots so that there would be an articulating vertebral implant device on each side of the vertical medial plane defined by the spinous process of the superior and inferior vertebrae. By implanting two articulating implant devices in this way, the implant devices could provide support for each side of the spine (i.e., both the left and right sides) and the resulting resistance to rotational movement of the two devices acting together would simulate the body's own resistance through facet joints. For these reasons, Applicant's posterior implant process is able to substantially achieve the arthroplasty art's objective of implanting prosthetics which approximate the disc's natural movement, particularly in the lumbar region, while allowing the surgeon to make his or her incisions much closer to the damaged disc tissue than is possible with the standard anterior approach.

The fundamental differences between Applicant's arthroplasty process and Michelson's fusion process has led to misunderstandings by the Examiner about the structure of Michelson's fusion devices and Michelson's process for implanting them. For example, the Examiner contends that Michelson's Short Distractor portion (120, 122) corresponds to Applicant's claimed "cushioning member." The purpose of Applicant's cushioning member is to

allow continued movement of the vertebrae in a way which generally approximates the replaced disc. By contrast, the purpose of Michelson's Short Distractor portion is to act as a temporary spacer after a partial discectomy is performed on one side of the disc so that the vertebrae do not collapse while the partial discectomy is being performed on the other side of the disc (see, Michelson patent, col. 19, lns. 21-50). If Michelson's Short Distractor portion (120, 122) were made of a flexible "cushioning" material, it would unable to perform its function of being a spacer. *Id.* Moreover, the description of Michelson's Short Distractor portion (120, 122) as having "sharp prongs 126" confirms that it is not a "cushioning member." (Michelson patent, col. 19, ln. 9).

Acknowledging that the Michelson patent fails to disclose "two permanently articulated vertebral implants that permanently allow continued movement of said vertebrae with respect to one another", the Examiner relies on the Ralph patent to try to provide the missing teaching. While the Ralph patent arguably discloses an articulating vertebral implant device, Applicant finds no teaching in the Ralph patent that Ralph's implant device can be inserted posteriorly, much less that two of Ralph's implant devices should be inserted posteriorly. Moreover, a careful inspection of the Ralph implant device demonstrates that the Ralph implant device is *unsuitable* for posterior insertion.

More specifically, the implant device shown in the Ralph patent is in the form of a wedge with one end being narrower than the other. If one tried to posteriorly insert Ralph's wedge-like implant into an intervertebral space with the narrower end of Ralph's wedge-like implant being inserted first, the wider end of Ralph's wedge-like implant would then tilt the spine forward. This would create a condition known in the art as kyphosis or "hunchback", which is

obviously *not* the desired result for spinal surgery. On the other hand, if one tried to first insert the wider end of Ralph's wedge-like implant into the intervertebral space using a posterior method, it is very doubtful that the wider end would fit through the small openings available in posterior surgery. Moreover, the protruding fingers sticking out of the wider end of Ralph's wedge-like implant, which could easily snag on bone or muscle tissue, make it evident that the wider end of Ralph's wedge-like implant should not be inserted first. For these reasons, even a cursory look at the structure of the wedge-like Ralph implant makes it apparent that the Ralph implant is intended to be used in the standard anterior implant method where the narrower end of the wedge-like Ralph implant can be inserted into the intervertebral space first and thereby avoid causing kyphosis. Since neither the Michelson patent nor the Ralph patent, individually or in combination, teach Applicant's invention and, in fact, affirmatively teach away from Applicant's invention, Applicant's claims 21-23 and 25-30 are not "obvious" over the Michelson and/or Ralph patents. *McGinley, supra.*, 262 F.3d at 1354 (Fed.Cir. 2001)(prior art references which "teach away cannot serve to create a prima facie case of obviousness")

Applicant's claim 24 has been rejected under 35 U.S.C. § 103(a) as being obvious over the Michelson patent in view of the Ralph patent and Beer's U.S. Patent No. 5,458,642 ("Beer patent"). The Beer patent discloses a single articulating vertebral implant device. There is no teaching or suggestion in the Beer patent that Beer's implant device could be inserted posteriorly or that two such devices should be placed on each side of a vertical medial plane defined by the spinous process of the superior and inferior vertebrae. Indeed, by showing the placement of screws (15c, 15d) on the anterior side of the vertebrae (opposite the spinous processes) in Beer's Figure 3, it is evident that Beer's device is implanted using the standard

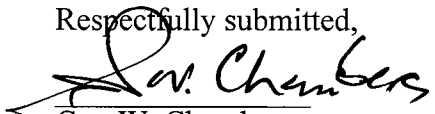
anterior approach. (see also, Beer patent, col. 4, lns. 65-66 - "FIG. 3 demonstrates the operation of the synthetic intervertebral disc during a backward bending of the spine"). Since the Beer patent, like the Michelson and Ralph patents, teaches away from Applicant's invention, the Beer, Michelson and Ralph patents cannot be combined to render Applicant's claim 24 "obvious."

Finally, Applicant has added new claims 31-34 to illustrate that, in some embodiments of Applicant's invention, the permanently articulating implant device can be assembled *in situ* (i.e., within the patient). This *in situ* assembly allows the surgeon to more easily fit the pieces of the implant device through the small openings available using the posterior method. In Applicant's view, none of the cited prior art even remotely suggests the *in situ* process for implanting permanently articulating implant devices using the posterior method as set forth on pages 18-19 of Applicant's specification and in Applicant's new claims 31-34.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 576-0200.

Respectfully submitted,



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